Act—Elimination of Market Entry Barriers (GN Docket No. 96–113).

Number of petitions filed: 2.

Subject: Implementation of the Non-Accounting Safeguards of Sections 271 and 272 of the Communications Act of 1934, as amended (CC Docket No. 96–149).

Number of petitions filed: 8.

Subject: Implementation of the Telecommunications Act of 1996; Accounting Safeguards Under the Telecommunications Act of 1996. (CC Docket No. 96–150).

Number of petitions filed: 8.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–6749 Filed 3–17–97; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

TIME AND DATE: 12:00 noon, Monday, March 24, 1997.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: March 14, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–6957 Filed 3–14–97; 2:44 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Availability of Final Environmental Impact Statement/Environmental Impact; Report for Proposed San Francisco Federal Building, San Francisco, CA

AGENCY: Public Buildings Service, United States General Services Administration.

ACTION: Notice.

SUMMARY: The United States General Services Administration (GSA) hereby gives notice that a joint Final Environmental Impact Statement/ Environmental Impact Report (EIS/EIR) has been prepared and filed with the United States Environmental Protection Agency (EPA) for the proposed construction of a new Federal Building within the City of San Francisco, California, in accordance with the Council of Environmental Quality regulations and the procedural provisions of the National Environmental Policy Act (NEPA). The proposed project involves the construction of a new Federal Building with 161 approximately 475,000 occupiable square feet of space (675,000 gross square feet) and onsite parking spaces. The purpose of this project is (1) to consolidate federal agencies housed in multiple locations in order to increase efficiency and to reduce the amount of government leased space and (2) to house law enforcement agencies that are not suitable as lease tenants. The preferred alternative for this project is the site located at 7th and Mission Streets.

DATES: Submit written comments on the Final EIS/EIR to GSA on or before April 21, 1997.

ADDRESSES: Mail written comments and requests for copies to Ms. Jane Woo, U.S. General Services Administration, Portfolio Management Division (9PT), 450 Golden Gate Avenue, 3rd Floor, San Francisco, California 94102.

FOR FURTHER INFORMATION CONTACT:

Ms. Jane Woo, (415) 522–3487.

(Authority: NEPA, the Environmental Quality Improvement Act of 1970, as amended (42 U.S.C. 4371 *et seq.*), sec. 309 of the Clean Air Act, as amended (42 U.S.C. 7609), and E.O. 11514 (Mar. 5, 1970, as amended by E.O. 11991, May 24, 1977)).

Dated: March 11, 1997.

Kenn N. Kojima,

Regional Administrator (9A).

[FR Doc. 97–6820 Filed 3–17–97; 8:45 am]

BILLING CODE 6820–23–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0504]

Determination of Regulatory Review Period for Purposes of Patent Extension; BAYTRIL®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BAYTRIL® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a

regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product BAYTRIL® (enrofloxacin). BAYTRIL® is indicated for chickens to control mortality associated with *Escherichia coli* susceptible to enrofloxacin, and for turkeys to control mortality associated with *E. coli* and *Pasturella multocida* (fowl cholera) susceptible to enrofloxacin. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BAYTRIL® (U.S. Patent No. 4,670,444) from Bayer Aktiengesellschaft and requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 21, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of BAYTRIL® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for BAYTRIL® is 4,334 days. Of this time, 648 days occurred during the testing phase of the regulatory review period, while 3,686 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: November 24, 1984. The applicant claims November 20, 1984, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's official acknowledgment letter assigning a number to the INAD was November 24, 1984, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the human drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: September 2, 1986. The applicant claims August 26, 1986, as the date the new animal drug application (NADA) for BAYTRIL® (NADA 140-828) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgment letter assigning a number to the NADA was September 2, 1986, which is considered to be the initially submitted date for the NADA.

3. *The date the animal drug was approved*: October 4, 1996. FDA has verified the applicant's claim that NADA 140-828 was approved on October 4, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 19, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 15, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97-6719 Filed 3-17-97; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 97D-0024]

Medical Devices; Immunotoxicity Testing Framework; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Immunotoxicity Testing Framework." This guidance will provide reviewers and manufacturers with a coherent strategy for assessing whether testing for potential adverse effects involving medical devices or constituent materials and the immune system is needed. The draft guidance will also aid in developing a systematic approach to such testing.

DATES: Written comments by June 16, 1997.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Immunotoxicity Testing Framework" to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0806 (toll free outside of MD 1-800-638-2041). Send two self addressed adhesive labels to assist that office in processing your requests. The draft guidance is also available via the World Wide Web at http://www.fda.gov/cdrh/draftgui.html. A text only version is also available from a VT-100 compatible terminal via the FDA bulletin board by dialing 800-222-0185 (terminal settings are 8/1/N).

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: John J. Langone, Center for Devices and Radiological Health (HFZ-113), Food and Drug Administration, 12709 Twinbrook Pkwy., Rockville, MD 20852, 301-443-7132.

SUPPLEMENTARY INFORMATION:

I. Background

In May 1995, FDA adopted the General Program Memorandum G95-1, an FDA-modified version of International Standard ISO-10993, entitled "Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing." It was pointed out that in addition to the general guidance for toxicity testing contained in that document, additional guidance might be needed for evaluation of specific organ or system toxicity. As a result, the Office of Device Evaluation, Center for Devices and Radiological Health, developed the